AMENDED IN ASSEMBLY JANUARY 3, 2000 AMENDED IN ASSEMBLY APRIL 26, 1999

CALIFORNIA LEGISLATURE-1999-2000 REGULAR SESSION

ASSEMBLY BILL

No. 827

Introduced by Assembly Member Baldwin

(Coauthor: Senator Vasconcellos)

February 24, 1999

An act to amend Sections 2051 and 2063 of, and to add Sections 852 and 2331 to, the Business and Professions Code, and to amend Sections 109300 and 110405 of, and to add Section 109251 to, the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

- AB 827, as amended, Baldwin. Healing arts: nonconventional treatment.
- (1) Existing law provides for the licensure and regulation of practitioners of the healing arts, as specified.

The bill would provide that various, specified licensed practitioners of the healing arts who elect to provide nonconventional treatment, as defined, shall inform their patient or the person responsible therefor, as specified, that the treatment is nonconventional as well as the possible benefits and risks, the foreseeable outcomes, the provider's education, training, and experience in relation to contemplated treatment, and any other truthful and nonmisleading information required in order to make

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informed and understanding determination regarding whether to undertake or refuse the recommended nonconventional treatment.

(2) Existing law specifies that the physician's and surgeon's certificate authorizes the holder to use drugs or devices in or upon human beings and to sever or penetrate the tissues of human beings and to use any and all other methods in the treatment of diseases, injuries, deformities, and other physical and mental conditions.

This bill would clarify that the certificate also authorizes the holder to diagnose, and would specify that the term "all other methods" applies to both conventional and nonconventional methods for those purposes.

(3) Existing law regarding the licensure and regulation of physicians and surgeons provides that it shall not be construed to discriminate against any particular school of medicine or surgery, school or college of podiatry medicine, or any other treatment.

This bill would further provide that that law shall not be construed to prevent the use of any system, methods, or mode of treating the sick or afflicted, whether conventional or nonconventional, for which the licensee has a reasonable expectation of efficacy.

(4) Existing law provides for the investigation and administrative adjudication of complaints against licensed physicians and surgeons.

This bill would provide that in the investigation of complaints involving issues of speciality clinical practice, investigators shall consult experts who are of the same specialty of practice, and in the investigation of complaints involving nonconventional clinical practice, investigators shall consult experts who dedicate a significant portion of their practice to nonconventional health care and diagnosis.

(5) Existing law specifically regulates the treatment of cancer and other specific serious diseases.

This bill would state that these provisions shall be construed to apply to the use of any health care remedy, procedure, or treatment not generally accepted by the majority of the health care practice community of the licensee, including the use of dietary supplements and homeopathy, as specified.

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(6) Existing law provides that the sale offering for sale, holding for sale, delivering, giving away, prescribing or administering of any drug, medicine, compound, or device to be used in the diagnosis, treatment, alleviation, or cure of cancer is unlawful and prohibited, as specified, unless an application with respect thereto has been approved under the Federal Food, Drug and Cosmetic Act, or an approved application has been filed with the Medical Board of California, as specified.

This bill would delete from the definition of that crime the unapproved treatment or alleviation of cancer.

(7) Under existing law, it is unlawful to disseminate any false advertisement of a food, drug, or cosmetic, as specified, except as to certain advertisements in professional periodicals or public health materials, or the drug or device has received approval for a specified use and is so advertised.

This bill would add to the above exemptions accurate and truthful reporting by a health care practitioner of the results of the administration of a medical treatment in a medical or scientific journal, or a professional seminar, convention, or meeting, or to other such persons as long as the person reporting receives no financial benefit of any kind from the manufacturer, distributor, or seller of any substance product used in that treatment.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- SECTION 1. Section 852 is added to the Business and 1 Professions Code, to read:
- 852. (a) All persons licensed pursuant to Chapter 4 3
- (commencing Section Chapter 5 with 1600),
- 5 (commencing Chapter with Section 2000), 6
- 6 (commencing with Section 2700). Chapter 6.6
- 7 (commencing with Section 2900), Chapter 11
- 4800), 8 (commencing with Section or Chapter 12 9 (commencing with Section 4925) of this division, or
- pursuant to the Osteopathic Act (set forth as Chapter 8
- 11 (commencing with Section 3600)) of this division, who

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1 elect to provide nonconventional treatment, shall inform elect to provide treatment that is nonconventional to 3 their practice, shall inform their patient, or his or her parent, guardian, conservator, or owner, as appropriate, 5 that the treatment is nonconventional to their practice, 6 as well as the possible benefits and risks, the foreseeable provider's education. outcomes. the experience in relation to the contemplated treatment, and any other truthful and nonmisleading information 10 that the patient, and his or her parent, guardian, conservator, or owner, as appropriate, would require in 12 order informed and understanding to make an 13 determination regarding whether to undertake or refuse recommended nonconventional treatment. information may include any or all of the following, as 15 16 appropriate: 17

- (1) Descriptions of the documented structure. 18 function, or mechanism by which the nonconventional remedy or treatment affects the body.
- (2) The existence of scientific literature that reports 21 upon or reviews medical claims in relation to the recommended treatment.
- (3) Information regarding the degree of acceptance of contemplated treatment by the general medical 24 the 25 community.
- (b) For purposes of this section, nonconventional 27 treatment has the meaning set forth in subdivision (b) of 28 Section 2051: "nonconventional treatment" means those methods of diagnosis. care treatment. acknowledged 30 intervention that are not 31 conventional, but that may be offered by some licentiates 32 of that healing art in addition to, or as an alternative to, 33 conventional treatment, and that provide a reasonable 34 potential for therapeutic gain in the patient's medical 35 condition not reasonably outweighed by the risk of those 36 *methods*.
- (c) For purposes of this section, "conventional 37 38 treatment" means those health care methods of diagnosis, 39 treatment, or intervention that are offered by most

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licentiates of that healing art as generally accepted methods or routine practice.

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- (d) This section shall not be construed to permit a licentiate to provide a specific treatment that the 5 licentiate is not authorized to provide under his or her 6 license.
- SEC. 2. Section 2051 of the Business and Professions Code is amended to read:
- 2051. (a) The physician's and surgeon's certificate 10 authorizes the holder to diagnose, to use drugs or devices in or upon human beings, to sever or penetrate the tissues 12 of human beings, and to use any and all other methods, 13 conventional or nonconventional, in the treatment of 14 diseases, injuries, deformities, and other physical and 15 mental conditions.
- (b) For purposes of this section, "nonconventional 17 treatment" means those health care methods of diagnosis, 18 treatment, or intervention that are not acknowledged to 19 be conventional, but that may be offered by some 20 licensed physicians in addition to, or as an alternative to, treatment, and that provide a 21 conventional medicine 22 reasonable potential for therapeutic gain in the patient's 23 medical condition not reasonably outweighed by the risk of those methods.
- (c) For purposes of this section, "conventional 26 treatment" means those health care methods of diagnosis, 27 treatment, or intervention that are offered by most 28 licensed physicians as generally accepted methods of routine practice, based upon medical training, 30 experience, and the peer-reviewed scientific literature. routine practice.
- SEC. 3. Section 2063 of the Business and Professions 32 33 Code is amended to read:
- 34 2063. Nothing in this chapter shall be construed so as 35 to discriminate against any particular school of medicine 36 or surgery, school or college of podiatric medicine, or any other treatment, or to prevent the use of any system, 38 method, or mode of treating the sick or afflicted, whether 39 <u>conventional or nonconventional, for which the licensee</u> 40 has a reasonable expectation of efficacy, nor shall it

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conventional or nonconventional, nor shall it regulate, prohibit, or apply to any kind of treatment by prayer, nor interfere in any way with the practice of religion.

SEC. 4. Section 2331 is added to the Business and 5 Professions Code, to read:

2331. In the investigation of complaints involving issues of specialty clinical practice, investigators shall consult experts who are of the same specialty of practice, investigation of complaints practice, clinical 10 nonconventional investigators consult experts who dedicate a significant portion of their practice to nonconventional health care and diagnosis.

SEC. 5. Section 109251 is added to the Health and 14 Safety Code, to read:

109251. This chapter shall be construed to authorize 16 the use of any health care remedy, procedure, or treatment not generally accepted by the majority of the 18 health care practice community of the licensee, which may include, but is not limited to, dietary supplements, 20 as defined in the Federal Food, Drug, and Cosmetic Act 21 (21 U.S.C. Sec. 321(ff)), and homeopathy, as the term is 22 used in the Federal Food, Drug, and Cosmetic Act (21) 23 U.S.C. Sec. 321(g)), for the alleviation and treatment of cancer.

SEC. 6. Section 109300 of the Health and Safety Code 26 is amended to read:

109300. The sale, offering for sale, holding for sale, 28 delivering, giving away, prescribing or administering of any drug, medicine, compound, or device to be used in 30 the diagnosis or cure of cancer is unlawful and prohibited unless (1) an application with respect thereto has been approved under Section 505 of the Federal Food, Drugand Cosmetic Act (21 U.S.C. Sec. 355), or (2) there has 34 been approved an application filed with the board setting 35 forth:

(a) Full reports of investigations that have been made 36 37 to show whether or not the drug, medicine, compound, or device is safe for the use, and whether the drug, medicine, compound, or device is effective in the use;

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(b) A full list of the articles used as components of the drug, medicine, compound, or device;

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- (c) A full statement of the composition of the drug, medicine, compound, or device;
- (d) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug, medicine, or compound or in the case of a device, a full statement of its composition, properties, and construction and the principle or principles of its operation;
- (e) Such samples of the drug, medicine, compound, or device and of the articles used as components of the drug, medicine, compound, or device as the board may require; and
- 15 (f) Specimens of the labeling and advertising 16 proposed to be used for the drug, medicine, compound, 17 or device.
- 18 SEC. 7. Section 110405 of the Health and Safety Code 19 is amended to read:
 - 110405. An advertisement that is not unlawful under Section 110390 is not unlawful under Section 110403 if it is any of the following:
 - (a) Disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of drugs or devices.
- 30 (b) An advertisement that a drug or device has a 31 specific curative or therapeutic effect on a condition, 32 disorder, or disease listed in Section 110403 if the drug or 33 device is approved or cleared for marketing for that 34 specific curative or therapeutic effect through any of the 35 following means:
- 36 (1) A new drug application approved pursuant to 37 Section 111500 or Section 505 of the federal act (21 U.S.C. 38 Sec. 355).

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31 that treatment.

- 1 (2) An abbreviated new drug application approved 2 pursuant to Section 505 of the federal act (21 U.S.C. Sec. 3 355).
- 4 (3) A licensed biological product pursuant to Section 5 351 of the Public Health Service Act (42 U.S.C. Sec. 262).
 - (4) An over the counter drug that meets the requirements of Part 330 of Title 21 of the Code of Federal Regulations.
- 9 (5) A new animal drug application approved under 10 Section 512 of the federal act (21 U.S.C. Sec. 360b).
- 11 (6) An abbreviated new animal drug application 12 approved pursuant to Section 512 of the federal act (21 13 U.S.C. Sec. 360b).
- 14 (7) A new device application approved pursuant to 15 Section 111550.
- 16 (8) A device premarket approval application 17 approved under Section 515 of the federal act (21 U.S.C. 18 Sec. 360e).
- 19 (9) A determination of substantial equivalence for a 20 device pursuant to Section 513(f)(1) of the federal act (21 U.S.C. Sec. 360c(i)).
- (c) An accurate and truthful reporting by a person licensed, certified, or registered pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code of the results of the administration of a medical treatment in a medical or scientific journal, or a professional seminar, convention, or meeting, or to other such persons as long as the person reporting receives no financial benefit of any kind from the manufacturer, distributor, or seller of any substance or product used in